UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA,
Plaintiff,

vs. **No. 1:19-cr-10040-JTF-1**

JEFFREY YOUNG,
Defendant.

MOTION AND MEMORANDUM TO CONTINUE

Comes now, Defendant by and through his counsel and Moves this Court to continue the trial currently set on May 16, 2022 to another date due to the pending change in the law related to the *mens rea* of the charge.[1] Furthermore, there are issues relating to the voidness of the statute due to vagueness and a possible implication of federalism relating to the federal government criminalizing a wholly-regulated state activity. A continuance would allow the law to be settled and to avoid protracted motion practice to preserve these new issues. The Government is opposed to a continuance.

MEMORANDUM OF LAW AND ARGUMENT
BEFORE THE SUPREME COURT

The Supreme Court of the United States has just heard oral arguments on the very issues hereto before this Court and will drastically alter the landscape of the Government's war on prescribers in Federal Court. The consolidated cases are full of issues, including but not limited to Federalism considerations of criminalizing state activity, the

[1] The SCOTUS heard oral arguments on the 1st of March in consolidated case number 20-1410, *Dr. Xiulu Ruan v. United States of America* where the Court will rule upon these issues. A ruling is expected in June or July.

unconstitutionality of 21 U.S.C. Sec. 841(a)(1) ("Controlled Substance Act" or just "CSA") due to vagueness, and whether the good-faith defense is a subjective or, as in the Sixth Circuit, an objective standard. What seems clear from the grant of the *writ* is that the Court will strike down the pattern jury instructions used in the Sixth Circuit.[2]

What is questionable is whether the Court will accept the federalism issues and remove cases like this from the federal court system.

I. The current "objective" good faith standard used in the Sixth Circuit will likely be rejected by the Court.

The current Sixth Circuit jury instruction (emphasis added below) and the instructions used in this district[3] use the following language for the good-faith defense:

> In making medical judgments concerning the appropriate treatment of an individual, practitioners do have discretion to choose among a wide range of available options, and so if a practitioner writes a prescription in "good faith" in the course of medically treating a patient, then the doctor has distributed the drug lawfully. In this context, "good faith" has a specific meaning. It means that a defendant engaged in an *honest* exercise of what he should *reasonably* believe to be proper medical practice. *This means that a physician's own individual treatment methods or his/her own personal belief that the prescribed drugs were beneficial to the patients do not, by themselves, constitute good faith. Instead, to constitute "good faith," the practitioner must be acting in a reasonable attempt to comply with the law*.
>
> The defendant does not have to prove to you that he acted in good faith. Instead, the *burden of proof is on the government to prove to you beyond a reasonable doubt that the defendant acted outside the course of usual professional practice without a legitimate medical purpose.* In considering whether a defendant

[2] I conferred with Counsel for Kahn and he feels confident that there will be a favorable opinion for the defense. Attorney Beau Brindley of Chicago has appeared in this district in the past.
[3] And the instructions requested by the government in previous prescription drug cases in this district. See, U.S. v. James Litton, CR. NO. 19-cr-20083-SHL.

> acted with a legitimate medical purpose in the usual course of professional practice[4], you should consider all of the defendant's actions and the circumstances surrounding them.

This is the Objective standard of the good-faith defense which completely collapses under the use of the "reasonable" and "reasonable attempt" language. This creates a situation where simple negligence and malpractice is sufficient to convict healthcare providers. This instruction makes no sense as a provider that "acted within the course of usual professional practices" and/or "with a legitimate medical purpose" does not need a good-faith defense. He didn't do anything wrong. Good faith is meaningless in that situation.

The issue before the Supreme Court is whether a physician can be convicted under the CSA unless they acted without a good-faith medical purpose. A conviction under the CSA requires that the defendant act "knowingly or intentionally." 21 U.S.C. § 841(a)(1). The statute's text, structure, history, and implementing regulations all confirm that this *mens rea* requirement insulates physicians with a *subjective* good faith belief that their prescription serves a medical purpose; an *objective* good faith (an oxymoron) instruction fails to distinguish ordinary malpractice from federal criminal conduct.

The subjective good-faith "medical purpose" standard as argued to SCOTUS this term is confirmed by the plain language of the CSA's implementing regulations. The CSA delegates to the Attorney General the power to authorize physicians to prescribe

[4] Actually this ends up being a complete misstatement of the law as the language is "not for legitimate medical purpose" and/or "outside the usual course of professional medical practice." Strangely, this language isn't even included in the statutory crime, but contained in regulations. One of the issues before the SCOTUS includes whether the Government must prove a violation of Sec. 841 with the conjunctive or disjunctive "and/or." This question impacts jury instructions and necessary proof at trial and is another reason to continue the trial.

controlled substances unless "inconsistent with the public interest." 21 U.S.C. § 823(b), (e). Once authorized, doctors may "possess, manufacture, distribute, or dispense such substances or chemicals . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." Id. § 822(b). But the CSA was also clear that regulations could not give federal officials the power "to exercise supervision or control over the practice of medicine or the manner in which medical services are provided." Id. § 823(g)(2)(H)(i). The Attorney General exercised that delegated authority by promulgating 21 C.F.R. § 1306.04(a). See *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006) (Section 1306.04(a) "does little more than restate the terms of the statute itself."). Section 1306.04(a) defines a "prescription" as one "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." (emphasis added). Section 1306.04(a) strongly supports the "medical purpose" test in two related ways. First and most obviously, it expressly defines a "prescription" as one "issued for a legitimate medical purpose." Reinforcing that first pillar is the second: only a prescription outside the "individual practitioner['s]" own practice—"his professional practice," not the norms of the profession as a whole—is proscribed. (emphasis added).

The CSA's statutory and legislative history confirm that prescribing physicians must be permitted to advance a robust good faith defense based on the physician's medical purpose. The CSA's predecessor statute, the Harrison Narcotics Act, closely tracked the language that delineates the scope of a physician's "authorization" under the CSA. In particular, it regulated the distribution of narcotic drugs, excepting "dispensing or distribution . . . *to a patient by a physician* . . . regularly registered under this act *in the*

course of his professional practice only." *United States v. Doremus*, 249 U.S. 86, 91 (1919) (quoting Harrison Act § 2(a), 38 Stat. 785) (emphasis added).

The Supreme Court's precedents construing the Harrison Act underscore that physicians may not be convicted as federal felons unless they act without a medical purpose. Soon after the Harrison Act's passage in 1914, this Court interpreted Section 2's general prohibition to apply to physicians who prescribed without a medical purpose. In assessing one physician's sufficiency-of-the-evidence challenge, the Court explained that a physician could be convicted if he prescribed to addicts "for the mere purpose, as the jury might find, of enabling such persons to continue the use of the drug, or to sell it to others." *Jin Fuey Moy v. United States*, 254 U.S. 189, 193 (1920). The Court also rejected as a "perversion of [the] meaning" of "a physician's prescription" (and therefore outside Section 2(a)'s exemption) a prescription issued not "in the course of professional treatment in the attempted cure of the habit, but . . . for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use." *Webb v. United States*, 249 U.S. 96, 99 (1919).

Five years later, in *Linder v. United States*, 268 U.S. 5 (1925), the Court reinforced the point. Although the "[m]ere pretense" of bona fide medical purpose could not insulate a physician from prosecution, *Id*. at 18, the Court vacated Dr. Linder's conviction because a physician who prescribes "in good faith" and without a "conscious design to violate the law" may not be convicted. *Id*. at 17. *Linder*'s holding is especially notable for two reasons. First, a separate section of the Act—Section 8, covering possession of narcotics—expressly provided for a good faith defense, whereas Section 2 did not, *Id*. at 14. That distinction did not deter the Court from applying a robust good

faith standard in Dr. Linder's favor. Second, the Court had previously held that Section 2's general prohibition was a strict liability offense. See *United States v. Balint*, 258 U.S. 250, 253-254 (1922). That, too, did not dissuade the Court from setting aside Dr. Linder's drug trafficking conviction because he lacked a "conscious design to violate the law."

In 1970, Congress enacted the CSA in an effort to "devise a more flexible penalty structure than that used" previously, *United States v. Moore*, 423 U.S. 122, 132 (1975), while also "strengthen[ing] . . . existing law enforcement authority in the field of drug abuse. *ibid*. (quoting Pub. L. No. 91-513, 84 Stat. 1236 (1970) (preamble)). But Congress gave "no indication" that the new statute brought a "sharp departure," *Moore*, 423 U.S. at 132, from the longstanding good faith defense endorsed by *Linder* and its progeny. For one, if Congress had wanted to eliminate this important *mens rea* protection, it would have spoken clearly; it did the opposite, requiring that unauthorized prescribing be "knowing or intentional," 21 U.S.C. § 841(a)(1). And as this Court explained in *Moore*, the CSA also embodies the policy that "physicians be allowed reasonable discretion in treating patients and testing new theories." 423 U.S. at 143. Consistent with that principle, Dr. Moore's jury instructions (implicitly approved by the Court) provided that Dr. Moore could be convicted only if he acted "other than in good faith" and did not make at least "'an honest effort' to prescribe . . . in compliance with an accepted standard of medical practice." *Id*. at 139, 142 n.20.

Since *Moore*, this Court has confirmed that Section 841(a)(1)'s application to physicians is narrow and targeted; it is not a tool for regulating medical practice by punishing doctors who practice bad medicine in good faith. In assessing the federal government's attempt to define the phrase "legitimate medical purpose," the Court

explained that "[t]he statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Oregon*, 29 546 U.S. at 269-270. But the CSA "manifests no intent to regulate the practice of medicine," *Id*. at 270, beyond prohibiting doctors from acting "as a drug 'pusher' instead of a physician." *Id*. at 269 (quoting Moore, 423 U.S. at 143).

The proper standard, then, is one that separates physicians operating at the fringes of medical innovation from those who abandon medicine entirely to engage in "conventional[ ]" "drug dealing and trafficking," *Oregon*, 546 U.S. at 270. A physician may not be convicted if she believes in good faith that her prescription has a legitimate medical purpose. This good faith defense must look only to the physician's subjective belief—eschewing both constructive knowledge and reference to general professional norms.

No other standard is up to the task of "separat[ing] wrongful conduct from otherwise innocent conduct." *Elonis v. United States*, 575 U.S. 723, 736 (2015) (quoting *Carter v. United States*, 530 U.S. 255, 269 (2000)). Requiring a physician's good faith belief to be "reasonable" imposes negligence liability— criminalizing and federalizing malpractice. And measuring good faith by reference to objective standards is both inconsistent with the statute and regulation and insufficiently protective of physicians' "traditional[ ]" and "widely accepted," *Staples v. United States*, 511 U.S. 600, 612 (1994) discretion in treating patients and "testing new theories," *Moore*, 423 U.S. at 143. To be sure, a physician's claim that he prescribed with a good faith medical purpose may not be credible. But that is a question to be resolved by the jury, which is free "not [to] believe

him," *Moore*, 423 U.S. at 143. 30 See *Morissette v. United States*, 342 U.S. 246, 263 (1952) ("The purpose and obvious effect of doing away with the requirement of a guilty intent is to ease the prosecution's path to conviction, to strip the defendant of such benefit as he derived at common law from innocence of evil purpose, and to circumscribe the freedom heretofore allowed juries.").

The "medical purpose" test the SCOTUS petitioners' are proposing to the Court is not meaningfully different from the so-called "subjective" good faith standard adopted by the First, Seventh, and Ninth Circuits. *United States v. Feingold* is the leading articulation of the subjective standard. There, the Ninth Circuit, relying on *Moore*, held that the government is required to prove "that the practitioner intentionally has distributed controlled substances for no legitimate medical purpose and outside the usual course of professional practice." 454 F.3d 1001, 1010 (2006) (emphasis added); id. at 1011 ("standard for criminal liability under § 841(a) requires more than proof of a doctor's intentional failure to adhere to the standard of care"). This standard asks whether a doctor's prescription conforms to what she believes is a generally accepted standard of medical practice and is serving what she believes to be a legitimate medical purpose. Failure to prove either of those requirements beyond a reasonable doubt requires acquittal. Were it otherwise, the Ninth Circuit has said, juries could convict "solely on a finding that [a physician] has committed malpractice," *Id*. at 1010, 31 rather than convicting only when a physician "ceases to be a physician at all," *Id*. at 1011.

"Good faith," by its nature, is a subjective concept. It asks about the state of the defendant's mind, not the objective nature of his conduct. By contrast, a requirement that the doctor's good faith be "reasonable" is, at bottom, a negligence standard— which is

not the level of "culpability . . . we usually require in order to impose criminal liability." *Arthur Andersen LLP v. United States*, 544 U.S. 696, 706 (2005). The traditional rule is that a defendant must "know the facts that make his conduct fit the definition of the offense." *Elonis*, 575 U.S. at 735 (emphasis added) (quoting *Staples*, 511 U.S. at 608 n.3). By contrast, a "reasonableness" qualifier converts good faith into constructive knowledge—and in the process disregards our law's traditional "belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil," *Morissette*, 342 U.S. at 250. It is also incompatible with other CSA provisions that impose a higher standard (recklessness) yet impose far less drastic penalties.

The Sixth Circuits standards of objective honest effort (e.g., from the standard jury instructions "honest exercise of what he should reasonable believe…") fails to separate out malpractice from criminal activity and effectively removes any protections of a good faith defense. As the Court explained in rejecting a similar "reasonableness" construction of the federal-threats statute, a "'reasonable person' standard is a familiar feature of civil liability in tort law, but is inconsistent with 'the conventional requirement for criminal conduct—awareness of some wrongdoing.'" *Elonis*, 575 U.S. at 737-738 (quoting *Staples*, 511 U.S., at 606- 607). "Having liability turn on" whether a physician's good faith belief in her medical purpose is "reasonable"—"regardless of what the [physician] thinks—reduces culpability on the all-important element of the crime to negligence." *Id*. at 738 (quotation marks omitted).

II. The argument has been made to the Supreme Court that principles of federalism require the Court to limit and narrow prosecutions of prescribers under the CSA.

Federalism has been expressly raised in the *writ* before the Court arguing that the "objective" good faith standard presents serious federalism concerns. "It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there"—indeed, that is "a vital part of a state's police power." *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954). This is particularly true with respect to physicians, "whose relations to life and health are of the most intimate character." *Hawker v. New York*, 170 U.S. 189, 194 (1898). It is thus "well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977) (collecting cases).

Interpreting the CSA to "regulate[ ] medical practice beyond prohibiting a doctor from acting as a drug 'pusher' instead of a physician," *Oregon*, 546 U.S. at 269, would vastly expand federal regulation of medicine. And a regime that imposes criminal liability based on simple negligence (or, as in the Eleventh Circuit, what amounts to strict liability) would do just that. Nothing in the CSA suggests an intent to replace medical boards and damages awards with United States Attorneys and prison terms. Indeed, far from displacing the States' regulation of medicine, "[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers." *Id*. at 270. Confirming the point: Congress did specifically displace State standards in one discrete area—the treatment of addicts. See *Id*. at 271-272 (discussing 42 U.S.C. § 290bb-2a). When Congress wants to regulate medical practice, rather than punish conventional "drug dealing and trafficking," it "does so by explicit language in the

statute." *Id*. at 270, 272. Beyond seriously altering the relationship between the States and the federal government, extending Section 841(a)(1) sanctions to doctors who act "unreasonably" would threaten a "fundamental[ ] chang[e]" in "the relation between the citizen and the Federal Government," *NFIB v. Sebelius*, 567 U.S. 519, 555 (2012) (opinion of Roberts, C.J.).

Physicians' autonomy is only one side of the coin. There is also the freedom of citizens to choose among physicians and treatment options, subject to local regulation of medical practice. The *in terrorem* effect of overzealous CSA prosecutions has already disrupted this balance, depriving chronic pain patients of medical choice and affecting their quality of life. Deference to the traditional doctor-patient relationship is especially important for sufferers of chronic pain—pain is by nature unusually subjective and often cannot be assessed using scans or diagnostic tests.

III. Justice Alito raised the issue of what actually is an element of the crime, possibly upsetting all prosecutions under the CSA of prescribers.

Furthermore, Justice Alito raises a thorny problem when he discusses his problems with Sec. 841 of the CSA.

> [W]hat disturbs me about some of the arguments -- well, many things disturb me about some of the arguments is the ungrammatical reading of the statute itself. The second is the idea that the "except [as authorized by this subchapter]" clause is an element. If it's an element, it has to be pled in the indictment . . . . [or] they would be invalid if they don't allege that. So these -- these Petitioners would not only be entitled potentially to a new trial, they'd be entitled to have the indictments dismissed, and all the other indictments would be -- that have been provided here have been -- have been flawed.

Considering the issue of the very nature of the elements of the crime and possible clarification from the Court, this motion should be granted solely on this issue.

IV. In another argument, the Court struggled with issues of vagueness as it attempts to apply the CSA to Practitioners.

Likewise, before the Court was the issue of vagueness. The argument was that the "Usual Course" and "Medical Purposes" prongs must be read in the conjunctive. When unmoored from the purpose for which a prescription was issued, "Usual Course" becomes unconstitutionally vague. Whether a doctor is acting "outside the scope of professional practice" and whether a doctor is acting "without a legitimate medical purpose" are two very distinct and separate questions. First, even those circuits finding that the "usual course" prong carries no scienter hold that the "medical purpose" prong requires the government to prove actual knowledge. *Kahn*, 989 F.3d at 825; *United States v. Tobin*, 676 F.3d 1264, 1283 (11th Cir. 2012); *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986).

Second, the "usual course" prong does not consider whether the prescriptions were actually helping to treat a patient's pain. While "legitimate medical purpose" focuses on (1) a doctor's intent in issuing the prescription, and (2) whether the prescription was beneficial to the patient, "usual course of professional practice" focuses on the manner in which the prescription was issued, and the procedures employed: Did the doctor conduct only cursory physical examinations? Does the doctor provide patients with pain contracts? Does the doctor keep sufficiently complete medical records? *United States v. Ruan*, 966 F.3d 1101, 1139 (11th Cir. 2020) (cert. granted, and consolidated with the instant case, 142 S. Ct. 457 (2021) (U.S. Nov 5, 2021) (No. 20-1410)); *United*

States v. Naum, 832 F. App'x 137, 142 (4th Cir. 2020) (petition pending before this Court, *Naum v. United States*, No. 20-1480).

Defining "usual course" based exclusively on the procedures a doctor employs without any reference to "medical purpose" renders the phrase indeterminant as to both how the standard should be measured, and the degree of compliance required. This dual indeterminacy is exactly the type of indeterminacy SCOTUS has found to be unconstitutionally vague. *Johnson*, 135 S. Ct. at 2558 ("By combining indeterminacy about how to measure the risk posed by a crime with indeterminacy about how much risk it takes for the crime to qualify as a violent felony, the residual clause produces more unpredictability and arbitrariness than the Due Process Clause tolerates.").

Uncertainty as to how "usual course" ought to be measured is sufficient to give rise to significant vagueness concerns. In *Johnson*, this Court held that the residual clause of the of the ACCA was unconstitutionally vague because of "grave uncertainty about how to estimate the risk posed by a crime." *Johnson v. United States*, 576 U.S. 591, 597 (2015). With the substitution of just a couple of words, the Court's reasoning in *Johnson* is equally applicable here: "How does one go about deciding what kind of conduct is within the [usual course of professional practice]? "A statistical analysis [of doctors]? A survey? Expert evidence? Google? Gut instinct?" *Id*. Similarly, in *Colautti v. Franklin*, this Court held a statute criminalizing abortion to be unconstitutionally vague because it did not indicate whether "sufficient reason" should be judged from the perspective of the treating physician or a "cross-section of the medical community." 439 U.S. 379, 393-94 (1979). Unless one can identify the standards by which a doctor is to be judged, it is

difficult to understand how a physician has "'fair notice' of the conduct" that renders a prescription criminal. *Papachristou v. Jacksonville*, 405 U.S. 156, 162 (1972).

As in *Johnson* and *Dimaya*, measuring "usual course" by a practitioner's compliance with general models of conduct leaves "unclear what threshold level" of compliance is required. *Sessions v. Dimaya*, 138 S. Ct. 1204, 1214 (2018). Without some basis for determining the threshold level of compliance necessary, nearly every doctor is at risk of prosecution. This "impermissibly delegate[s] basic policy matters" to prosecutors and juries for "resolution on an ad hoc and subjective basis." *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972). Unmoored from "medical purpose," the "usual course" prong allows "criminal sanctions . . . [to be] used, not to punish conscious and calculated wrongdoing at odds with statutory proscriptions, but instead simply to regulate business practices regardless of the intent with which they were undertaken." *Gypsum Co.*, 438 U.S. at 442.

CONCLUSION

Based on the numerous issues currently awaiting ruling in the Supreme Court of the United States, this Court should continue the trial to a date in the future.

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of March, 2022, I served a true and correct copy of the foregoing upon the person(s) listed below by the following method(s) of service:

[ ] Depositing it in the U.S. mail, first class postage prepaid and properly addressed;
[ ] Hand delivery;
[ ] Facsimile transmission
[**X**] Electronic Transmission - PACER

Jillian Willis
U.S. Department of Justice
Criminal Division, Fraud Section
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/s/ Claiborne H. Ferguson